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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

List of Accredited Persons; Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the list of persons who are accredited under certain circumstances to inspect eligible manufacturers of class II and class III devices in lieu of an FDA inspection. This list provides the identity of each accredited person and the particular activities for which the person is accredited. FDA is taking this action to implement provisions of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA).

ADDRESSES: This list is available on the Internet at *http://www.fda.gov/cdrh/ap-inspection/.* Submit a written request for copies of the List of Accredited Persons to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the list of accredited persons.

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FOR FURTHER INFORMATION CONTACT: John F. Stigi, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597, ext. 124.

SUPPLEMENTARY INFORMATION:

I. Background

MDUFMA (Public Law 107–250) was signed into law on October 26, 2002. Section 201 of MDUFMA adds a paragraph "g" to section 704 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 374), directing FDA to accredit third parties (accredited persons or APs) to conduct inspections of eligible manufacturers of class II or class III devices. Participation in the program is voluntary. Manufacturers may continue to have FDA perform inspections or, if eligible, they may utilize an accredited person. The new law requires FDA, within 180 days from the date MDUFMA was signed into law, to publish in the **Federal Register**, criteria to accredit or deny accreditation to persons who request to perform these inspections (section 704(g)(2) of the act). FDA published the criteria it used to accredit persons for the purpose of conducting inspections of eligible manufacturers of class II and class III devices in the **Federal Register** of April 28, 2003 (68 FR 22400).

The new law also directed FDA to accredit up to 15 third parties to conduct inspections by no later than 1 year after MDUFMA was enacted and to publish on the FDA Internet site a list of persons who are accredited (21 U.S.C. 374(g) (4)). Under the new provision, FDA must update this list to ensure that the identity of each accredited person, and the particular activities for which the person is accredited, is known to the public. Under this new provision, FDA must also update the list no later than 1 month after the accreditation of a person, or the suspension or withdrawal of accreditation,

or the modification of the particular activities for which the person is accredited.

FDA is currently developing guidance to help establishments determine whether they are qualified to participate in the third party inspection program. Because all accredited persons will have to complete training before conducting independent inspections under the new program, these APs will not be available to companies for several months. FDA plans to make the guidance available before the APs have completed the training. In the meantime, any company that is interested in participating in the third party inspection program may contact the contact person (see **FOR FURTHER INFORMATION CONTACT**) to get more information about eligibility.

II. Electronic Access

Persons interested in obtaining a copy of the list of accredited persons may also do so by using the Internet. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. The list of accredited persons is available at *http://www.fda.gov/cdrh/ap-inspection/*.

To receive the list of accredited persons by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1500) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Dated: 10/29/03

October 29, 2003.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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